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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,730	11/18/2003	George F. Fattman	CV0326 NP	4899
26079	7590	08/11/2005	EXAMINER	
BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			HILL, LAURA C	
		ART UNIT		PAPER NUMBER
				3761

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,730	FATTMAN, GEORGE F.	
	Examiner	Art Unit	
	Laura C. Hill	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are; a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/18/03 & 4/18/04</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Ostomy pouch attachment adhesives such as polysiloxane that are resistant to stomal effluent.

Claim Interpretation

3. It is noted that the phrase 'material having silanol functionality' as recited in claim 10 is interpreted to mean the functionality results in the replacement of one or more trimethylsiloxy groups with hydroxyl groups as found on page 13 of the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by McInally et al. (US 4,831,070). Regarding claims 1-2 and 4-5 McInally et al. discloses a pressure sensitive adhesive polydiorganosiloxane to form a seal between the stoma of an ostomy patient and an attached appliance having at least one component (col. 2, II. 60-66, col. 8, II. 34-48).

Regarding claim 3 McInally et al. discloses the device as discussed above with respect to claim 1. McInally et al. further discloses employing hydrocolloids in an amount up to about 30% of the elastomeric pressure sensitive adhesive and therefore capable of having the range percentages claimed (col. 6, ll. 42-48). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Regarding claims 12-13 McInally et al. discloses the device as discussed above with respect to claim 1. McInally et al. further discloses the use of additional property modifiers such as orthosilicates, plasticizers, co-solvents and other silicone or organic pressure sensitive adhesive materials (col. 5, ll. 23-36, col. 6, ll. 21-25).

3. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Abber (WO 86/00532 A1). Abber discloses pressure sensitive adhesives such as dimethyl diphenyl siloxane gum with dimethyl siloxane gum/plasticizing oil and an organopolysiloxane resin for use on human skin for therapeutic devices (page 1, lines 13-16, page 5, lines 7-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 8-9, 11 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McInally et al. (US 4,831,070). Regarding claims 8-9 McInally et al. discloses the device as discussed above with respect to claim 1. McInally et al. further discloses the adhesive composition may further include a trimethyl-endblocked polydimethylsiloxane resin (col. 6, ll. 3-6). McInally et al. does not expressly disclose the adhesive is blended with a *silicate* resin. One would be motivated to modify the polydimethylsiloxane resin with a silicate resin since both resins contain silicone, oxygen and CH₃ groups that are blended with adhesives. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the resin of McInally et al., thus providing a silicate resin.

Regarding claims 11 and 15-18 McInally et al. discloses the device with a silicate resin and polydiorganosiloxane as discussed above with respect to claims 1 and 8. McInally et al. does not expressly disclose the ratio of resin to pressure-sensitive adhesive, a plasticizing component percentage, peel strength, or coat weight in the ranges claimed. The ratio of resin to pressure-sensitive adhesive is a result-effective variable since the value depends on the amount of resin and adhesive, respectively, are

utilized in the device. The plasticizing component of dry adhesive formulation percentage is a result effective variable since it depends on the solvent used. The peel strength is a result effective variable since the value depends on the resin to polymer ratio and the thickness of the adhesive as stated on page 16 of the instant specification. The coat weight is a result effective variable since it depends on the thickness of the adhesive and thus the amount of adhesive used on a given substrate. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify McInally et al. to have the ratio, peel strength, plasticizing component, and coat weight values claimed, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 19-20 McInally et al. discloses the at least one component ostomy device as discussed above with respect to claim 1. McInally et al. does not expressly disclose the ostomy device includes a separable pouch and body wafer. Ostomy pouches including separable pouch and body wafer components are well known to those of ordinary skill in the art as supported by US 2,662,525 (figures 1 and 3); US 2,341,984 (figures 1-2); US 3,385,298 (figure 1); US 4,411,659 (figure 1); US 4,445,898 (figure 1); US 4,890,608 (figure 1); US 5,125,917 (figure 1). Therefore, one would have been motivated to modify the ostomy device of McInally et al. with the separable pouch and body wafer components since all the references teach ostomy devices with separable components that are attached to one another. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify

the ostomy device of McInally et al., thus providing a two-piece separable ostomy device having a polysiloxane adhesive.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abber (WO 86/00532 A1) in view of Lin (US 5,580,915). Abber discloses pressure sensitive adhesives such as dimethyl diphenyl siloxane gum with dimethyl siloxane gum/plasticizing oil and an organopolysiloxane resin for use on human skin for therapeutic devices (page 1, lines 13-16, page 5, lines 7-11). Abber does not expressly disclose the resin has a substituted hydroxyl group. Lin discloses a composition for a pressure-sensitive adhesive having good peel and tack adhesion properties with a 'silanol reactive' hydroxyl group (col. 3, ll. 7-11, ll. 64-67, col. 4, ll. 40-55). One would be motivated to combine the adhesive of Abber with the silanol functionality of Lin since both references disclose the composition of pressure-sensitive adhesives with good adhesion properties. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the adhesive of Abber, thus providing an adhesive with silanol functionality.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over McInally et al. (US 4,831,070) as applied to claim 1 above, and further in view of Abber (WO 86/00532 A1). McInally et al. discloses the ostomy device having a polysiloxane-type adhesive as discussed above with respect to claim 1. McInally et al. does not expressly disclose a medicament for skin treatment or protection. Abber discloses the transdermal device having a polysiloxane-type adhesive as discussed above with respect to claim 1. Abber further discloses the adhesive on the transdermal device permits medication to

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pass from the device, through the adhesive and into the skin (page 8, ll. 23-27). One would be motivated to modify the adhesive-attaching ostomy device of McInally et al. with the medicament-permitting adhesive of Abber since both references disclose polysiloxane-type adhesives suitable for attaching devices to the skin. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the adhesive-attaching ostomy device of McInally et al., thus providing an ostomy device containing a medicament.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Keyes (US 5,709,673) is cited for showing a separable two-piece ostomy pouch 14 having a hydrocolloid adhesive. O'Malley (US 4,039,707) is cited for showing an alkylarylopolysiloxane gum pressure-sensitive tape.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
PRIMARY EXAMINER





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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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Commissioner for Patents